



# MLN Matters®



Information for Medicare Fee-For-Service Health Care Professionals

Related Change Request (CR) #: CR3797

MLN Matters Number: MM3797

Related CR Release Date: April 15, 2005

Related CR Transmittal #: 32

Effective Date: March 15, 2005

Implementation Date: May 16, 2005

## *Updated Requirements for Autologous Stem Cell Transplantation (AuSCT) for Amyloidosis*

**Note:** This article was updated on February 7, 2013, to reflect current Web addresses. All other information remains unchanged.

### Provider Types Affected

Physicians and providers billing Medicare carriers and intermediaries for AuSCT

### Provider Action Needed

This article is based on information contained in Change Request (CR) 3797, which informs physicians and providers that, effective for services on or after March 15, 2005, High Dose Mephalan (HDM) and Autologous Stem Cell Transplantation (AuSCT) is reasonable and necessary for all Medicare beneficiaries with primary Amyloid Light chain (AL) amyloidosis who meet the following criteria:

- 1) Amyloid deposition in two or fewer organs; and
- 2) Cardiac left ventricular ejection fraction (EF) greater than 45 percent.

Primary AL amyloidosis is covered for all beneficiaries who meet the above criteria regardless of age. All forms of non-primary (AL) amyloidosis remain non-covered.

### Background

Stem cell transplantation is a process by which stem cells are harvested from either a patient's or a donor's bone marrow (or peripheral blood) for intravenous infusion. Autologous Stem Cell Transplantation (AuSCT) is a technique for restoring a patient's stem cells using the patient's own previously stored cells (ICD-9-CM procedure code 41.01, 41.04, 41.07, and 41.09 and CPT-4 code 38241).

AuSCT **must** be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (High Dose Chemotherapy (HDCT)) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients who have an inherited or acquired deficiency or defect.

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### *Coverage Policy Changes*

For Medicare beneficiaries age 64 years or older who have primary Amyloid Light chain (AL) amyloidosis (ICD-9-CM 277.3), the Centers for Medicare & Medicaid Services (CMS) previously had a national non-coverage policy for High-Dose Melphalan (HDM), together with Autologous Stem Cell Transplantation (AuSCT). This non-coverage policy was based on the lack of sufficient data to establish definitive conclusions regarding the efficacy of AuSCT, and for those beneficiaries age 63 years or younger, coverage of HDM/AuSCT was left to the local Medicare carrier's/intermediary's discretion.

However, CR3797 informs physicians, providers, and suppliers that (effective for services on or after March 15, 2005) when recognized clinical risk factors are employed to select patients for transplantation, HDM together with AuSCT is reasonable and necessary for Medicare beneficiaries of **any age group** with primary AL amyloidosis who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and
- Cardiac left ventricular Ejection Fraction (EF) greater than 45 percent.

Primary AL amyloidosis is covered for all beneficiaries who meet the above criteria regardless of age, and all forms of non-primary (AL) amyloidosis remain non-covered.

To clarify existing coverage, AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (high dose chemotherapy (HDCT)) and/or radiotherapy used to treat various malignancies.

Please refer to the National Coverage Determinations Manual (Pub. 100-03), Section 110.8.1 for complete coverage guidelines; and the Medicare Claims Processing Manual (Pub. 100-04), Chapter 3, Section 90.3.2 (FI), plus Chapter 32, Section 90-90.6 (Carrier) for complete claims processing guidance.

### *Updates to Medicare Claims Processing Manual*

CR3797 updates the Medicare Claims Processing Manual (Pub.100-04), Chapter 3, Section 90.3.2 (FI claims) and Chapter 32, Section 90.3 (carrier claims) with the new coverage guidelines for primary amyloid light chain (AL) amyloidosis for high-dose melphalan together with autologous stem cell transplantation (HDM/AuSCT).

The criteria for multiple myeloma (Durie-Salmon) within the Fiscal Intermediary (FI) section is also revised to coincide with the Nation Coverage Determination Manual (NCD) (Pub. 100-03), Section 110.8.1 and the non-coverage guidelines have been updated to remove the age requirement language to in Chapter 32, Section 90.3.2.

In addition, CMS removed reference to revenue code 0891 in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 3, Section 90.3.3), since that revenue code no longer exists. CMS also removed the reference to physicians that does not belong in the hospital chapter. All other information within the claims processing manual remains the same.

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## Additional Information

For complete details (including the manual updates listed in the previous section), please see the official instruction issued to your carrier/intermediary regarding this change. The instructions may be viewed by going to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R32NCD.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R526CP.pdf> on the CMS website.

One file will contain the National Coverage Determination manual changes and the other will contain the changes to the Medicare Claims Processing Manual.

If you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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